DING HWA CO., LTD.
漢弓股份有限公司

APR 2 8 2014

Sec. 5: 510(k) Summary – Ding Hwa AS-XXXX (Family Series) Suction Pump

Date Summary was Prepared	December 25, 2013
510(k) Submitter	Ding Hwa Co. Ltd. #121 Sec. 3 Zhongshan Road Dacun, Chang-Hwa, Taiwan 51542
Primary Contact for this 510(k) Submission	Robert O. Dean Compliance Systems International, LLc. 1083 Delaware Rd. Buffalo, NY 14223 716.440.7362 compliancesystems@yahoo.com
Device Common Name	Powered suction pump
Trade Name	AS-XXXX Suction Pump (family series)
Device Product Codes and Classification Name	JCX, 21CFR878.4780, Powered suction pump
Predicate Device	EMG Suction Unit, Model SUA01-AXX Series 510(k)112421
Device Description	The AS-XXXX (FAMILY SERIES) suction pump is a portable AC-powered suction pump. The AS-XXXX (FAMILY SERIES) suction pump creates a negative pressure (vacuum) that draws fluids through a disposable suction catheter that is connected by suction tubing to a collection container. The suctioned fluids are then trapped in the collection container for proper disposal. The device must only be used on the order of a physician. If practiced outside of the hospital setting, the care giver must be trained by a certified healthcare professional and the training must be recorded and documented. The AS-XXXX (FAMILY SERIES) suction pump consists of an on/off switch, a pump unit, a power cord, a collection container, relief valve, pressure adjustment knob, pressure gauge, microbial filter, long intermediate tubing, short intermediate tubing, and suction tubing. Disposable suction catheters are not packaged with this device and must be purchased separately.
Intended Use	AS-XXXX Suction Pump is intended to be used to remove body fluids from a patient's airway or respiratory system.
Technological Characteristics	Ding Hwa AS-XXXX Suction Pump is of the same design, material and performance characteristics and intended use as the predicate device.
Summary of Testing	Ding Hwa AS-XXXX Suction Pump is substantially equivalent and meets the same acceptance criteria as the predicate device, EMG Suction Unit SUA01-AXX 510(k)112421. Non-clinical performance testing includes IEC 60601-1, 3rd Ed. MEDICAL ELECTRICAL EQUIPMENT - PART 1: GENERAL REQUIREMENTS FOR BASIC SAFETY AND ESSENTIAL PERFORMANCE, IEC 60601-1-2: Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility and ISO 10079-1 (2009): Medical suction equipment -- Part 1: Electrically powered suction equipment -- Safety requirements. All results of the testing met acceptance criteria.
Substantial Equivalence	The AS-XXXX Suction Pump described in this 510(k) submission are substantially equivalent in all specifications and performance compared to the predicate device identified in K112421 and do not raise any new types of safety and effectiveness issues when compared to the predicate device.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

April 28, 2014

Ding Hwa Company, Ltd.
Mr. Robert O. Dean
Compliance Systems International, LLC.
1083 Delaware Road
Buffalo, New York 14223

Re: K140031
Trade/Device Name: Ding Hwa Co., Ltd – AS-XXXX Suction Pump (Family Series)
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered suction pump
Regulatory Class: Class II
Product Code: JCX
Dated: March 26, 2014
Received: April 1, 2014

Dear Mr. Dean:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
140031

Device Name
Ding Hwa Co., Ltd – AS-XXXX Suction Pump (Family Series)

Indications for Use *(Describe)*
Intended Use: AS-XXXX Suction Pump is intended to be used to remove bodily fluids from a patient's airway or respiratory system.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Joshua C. Nipper -S

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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